WRP Asia Pacific Sdn Bhd

147817V

K040503

MAR 16 2004

SPECIAL 510(k) SUMMARY

1.0 Submitter:

Name:	WRP Asia Pacific Sdn Bhd
Address:	Lot 1, Jalan 3, Kawasan Perushaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Phone No.:	+60 3 8706 1486
Fax No.:	+60 3 8706 1485

Date of Summary Prepared: 25 FEB 2004

2.0 Contact Person:

Name:	Mr. Terence Lim
Phone No.:	+60 3 8706 1486
Fax No.:	+60 3 8706 1485

3.0 Modified Device Identification:

Trade Name:	1) Aloetouch, and 2) Multiple or Customers' Trade Name
Device Name:	Powder Free, Polymer Coated Polyisoprene Surgical Gloves, Sterile, Coated with Aloe Vera, Natural colour or Turquoise (Blue/Green) colour
Common Name:	Surgical Gloves
Classification Name:	Surgeon's Gloves (per 21 CFR 878.4460)

4.0 Identification of the Legally Marketed Device:

Class I Powder Free Synthetic rubber latex surgeon's gloves, 79KGO, that meets all the requirements of ASTM standard D 3577 – 01a^{E2} Type 2 and FDA 21 CFR 800.20.

5.0 Description of Device Modification:

The Powder Free, Polymer Coated Polyisoprene Surgical Gloves, Sterile, Coated with Aloe Vera, Natural colour or Turquoise (Blue/Green) colour is equivalent to the exiting model, i.e. Powder Free, Polymer Coated Polyisoprene Surgical Gloves, Sterile which had submitted and cleared under 510(k) number K032942.

The differences in this submission are:

a) With Aloe Vera coated on surgical gloves,
b) Without colour additive, i.e. natural colour or
c) With colour additive, i.e. turquoise (blue/green) colour.
   - Colour additive is added for Turquoise (Blue/Green) Surgical Gloves and will be subjected to design controls process whereby, risk assessment will be conducted to identify the hazards and estimate the risks of colour changed (Refer to Section 5 – Design Control Activities for the modified Device)

The modification of device does not affect the intended use of the device as well as it does not affect its safety and effectiveness. The indication for use and proposed labeling for the device are illustrated in subsequent sections.

The Powder Free, Polymer Coated Polyisoprene Surgical Gloves, Sterile, Coated with Aloe Vera, Natural colour or Turquoise (Blue/Green) colour meets all the requirements of ASTM standard D 3577 – 01a[E2] and FDA 21 CFR 800.20.

6.0 Intended Use of the Device:

The Powder Free, Polymer Coated Polyisoprene Surgical Gloves, Sterile, Coated with Aloe Vera, Natural colour or Turquoise (Blue/Green) colour are made of synthetic rubber latex intended to be worn by surgeons and/or operating room personnel to protect a surgical wound from contamination.

7.0 Summary of Technological Characteristics for the Modified Device:

The Powder Free, Polymer Coated Polyisoprene Surgical Gloves, Sterile, Coated with Aloe Vera, Natural colour or Turquoise (Blue/Green) colour are summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D 3577 – 01a^{E2}	Meets
Physical Properties	ASTM D 3577 – 01a^{E2}	Meets
Freedom from pinholes	ASTM D 3577 – 01a^{E2} FDA 21 CFR 800.20	Meets
Powder Residual	ASTM D 6124 – 01	Meets < 2 mg/glove
Biocompatability	Primary Skin Irritation in Rabbits	Passes (Not a primary skin irritant)
	Dermal Sensitization	Passes (Not a contact sensitizer)

8.0 Conclusion:

The Powder Free, Polymer Coated Polyisoprene Surgical Gloves, Sterile, Coated with Aloe Vera, Natural colour or Turquoise (Blue/Green) colour will perform according to the glove performance standards referenced in section 7 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2004

Mr. Terence Lim
Manager, QA/RA
WRP Asia Pacific Sdn Bhd
Lot 1, Jalan 3, Kawasan Perusahaan
Bandar Baru Salak Tinggi,
43900 Sepang,
Selangor Darul Ehsan,
MALAYSIA

Re: K040503
Trade/Device Name: Aloetouch Powder Free Polymer Coated Polyisoprene Surgical Gloves, Sterile Coated with Aloe Vera (Blue/Green) Color
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: February 25, 2004
Received: February 27, 2004

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

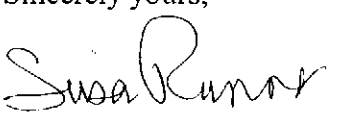
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRP Asia Pacific Sdn Bhd

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INDICATIONS FOR USE

Applicant: WRP Asia Pacific Sdn Bhd

510(k) Number (if known): K040503

Device Name: POWDER FREE, POLYMER COATED POLYISOPRENE SURGICAL GLOVES, STERILE, COATED WITH ALOE VERA, NATURAL COLOUR OR TURQUOISE (BLUE/GREEN) COLOUR

Indications For Use:

The surgeon's glove is a device made of synthetic rubber latex intended to be worn by surgeons and/or operating room personnel to protect a surgical wound from contamination.

Prescription Use ____ ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Martha O'Love
Interim Branch Chief/NCB

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K040503